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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,394	07/26/2001	Marc Gianotti	JM-009 CIP2	7774

7590

10/09/2003

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EXAMINER

THALER, MICHAEL H

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 10/09/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/916,394

Applicant(s)

GIANOTTI ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 32-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6,8,11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Claims 32-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 13.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, lines 4-5, "relative to a longitudinal axis of the stent" is confusing and inaccurate since the longitudinal axis of a curved stent is also curved.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 15, 16 and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 00/32241) in view of Van Oepen (WO 00/13611). Caro discloses a stent having a curvature along its length (page 3, lines 5-20 and page 10, lines 1-30) which is deployed within a blood vessel. The Caro specification fails to

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specifically indicate that the stent is adapted for expansion from a collapsed delivery configuration to an expanded deployed configuration. However, it was well known that stents are typically deployed in this fashion. For example, Van Oepen teaches that a stent should be adapted for expansion from a collapsed delivery configuration to an expanded deployed configuration (abstract) apparently so that it can be transported through a blood vessel, while collapsed, without harming it. It would have been obvious to make the Caro stent adapted for expansion from a collapsed delivery configuration to an expanded deployed configuration so that it too would have this advantage. As to claim 2, Van Oepen teaches that the stent may be self-expandable (noting col. 2, lines 16-21 of U.S. Patent 6,602,285 which is merely cited for its English language of the disclosure of WO 00/32241). As to claims 20-25, Caro fails to disclose the specific web structure of the stent. However, Van Oepen teaches that a stent should be so constructed so that it provides a very stable construction in the expanded state (col. 1, lines 36-56 of U.S. Patent 6,602,285). It would have been obvious to so construct the Caro stent so that it too would have this advantage. As to claims 26 and 27, Caro fails to disclose a balloon catheter to deploy the stent. However, Van Oepen teaches that a balloon catheter may be

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used to deploy a stent (col. 2, lines 16-21 of U.S. Patent 6,602,285) apparently so that the degree of expansion may be accurately controlled by the practitioner. It would have been obvious to use a balloon catheter to deploy the Caro stent so that it too would have this advantage. ~~As to claim 27-31, it certainly would have been obvious to make the shape of the balloon catheter similar to the shape of stent in order to fit appropriately within it, particularly since it was well known to match the shape and size of balloon catheter to the stent that surrounds it.~~

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 00/32241) in view of Van Oepen (WO 00/13611) as applied to claim 1 above, and further in view of Lukic et al. (5,709,703). Caro fails to disclose a delivery catheter having an inner and outer sheath to deploy the stent. However, Lukic et al. teach that a delivery catheter having an inner and outer sheath may be used to deploy a stent (col. 6, lines 31-60) apparently so that it can be easily deployed. It would have been obvious to use such a catheter to deploy the Caro stent so that it too would have this advantage. As to claim 14, Lukic et al. fails to disclose an imaging transducer on the delivery catheter. However, it was well known to include such an imaging transducer on an intravascular catheter so that it could provide an image of the

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interior of the blood vessel. It would have been obvious to include an imaging transducer on the Lukic et al. delivery catheter so that it too would have this advantage.

<sup>75</sup>  
Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 00/32241) in view of Van Oepen (WO 00/13611) as applied to claim 1 above, and further in view of Kula (EP 1042997). Caro fails to disclose the thickness of the stent changing along the longitudinal axis of the stent. However, Kula teaches that a stent should be so constructed in order to protect the artery or to provide increased radiopacity at the ends of the stent (col. 6, lines 6-10 and col. 9, lines 17-25). It would have been obvious to so construct the Caro stent so that it too would have this advantage.

<sup>76, 77</sup>  
Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 00/32241) in view of Van Oepen (WO 00/13611) as applied to claim 1 above, and further in view of Kitakoa et al. (6,174,326). Caro fails to disclose a coating on the stent. However, Kitakoa et al. teach that a coating should be on a stent in order to retard thrombus formation (abstract). It would have been obvious to provide a coating on the Caro stent so that it too would have this advantage.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note the abstract of Boylan et al. (6,572,646).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht  
September 26, 2003



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731